

**Participant Name:****Date:****Title of Study:** Boston Scientific Synergy Bioabsorbable Polymer Stent in Left Main PCI SOLEMN Study (Synergy OCT LEft MaiN)**Principal Investigator:** Mladen Vidovich, MD***JBVAMC INSTITUTIONAL REVIEW BOARD INFORMED CONSENT DOCUMENT*****Boston Scientific Synergy Bioabsorbable Polymer Stent in Left Main PCI SOLEMN Study (Synergy OCT LEft MaiN)****Principal Investigator: Mladen Vidovich, MD****Sponsor: Boston Scientific****INTRODUCTION**

You are being invited to take part in a research study that is being supported and conducted by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part in this study, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

PURPOSE OF THE STUDY

You are being asked to participate in this study because you have been diagnosed with symptomatic ischemic heart disease, caused by a plaque which blocks the flow of blood in your heart in one of your coronary vessels, called the Left Main Coronary (LMC) artery.

A stent is a small wire mesh tube that is placed in the arteries of your heart that have plaque in them. The stent is delivered to the artery on a small catheter (wire-like system). Once the stent is in the proper location, the stent is expanded to its full size by a small balloon. The expanded stent then pushes plaque out of the way and opens up the artery so that blood can flow through the artery again. One of the anticipated risks after the stent is placed, is that the blockage can reoccur in the same area, due to a scar that grows in around the stent during the process of healing.

This study is being done to assess the outcome of the patients with LMC disease after being treated with Boston Scientific Synergy Bioabsorbable Polymer Stent, and how efficient the stent prevents from narrowing of the vessel, or even causing a recurring blockage in the future.

In order to observe and to assess the healing of the vessel treated with this stent, we will use a technique called Optical Coherence Tomography (OCT), to directly observe the area previously blocked, with a special catheter, placed in the same manner as in the initial angiography. The procedure is detailed below.

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PROCEDURES

About 75 subjects will take part in this study at up to 10 different VA locations. Your participation in the study will be about 1 year. The entire study itself may last for about 3 years, so there is enough time for all subjects to be enrolled.

During this study, you will have:

- A baseline visit
- A follow up visit at 1 month after your initial procedure, completed in clinic or by phone.
- A follow-up visit at 3 months after your initial procedure, when the first study OCT will be performed.
- A follow-up office visit at 12 months after your initial procedure, when the second study OCT will be performed.

Details of Procedures:

The baseline visit occurs prior to your discharge from the hospital after you undergo angiography and receive the stent. This visit will include the following:

- An interview about your medical history
- A clinical assessment and physical examination
- Angina status (chest pain)
- Blood Draw to assess:
 - Complete Blood Count (CBC) (gives information about cells in the blood stream such as white blood cells, red blood cells and platelets)
 - Urea and Serum Creatinine (gives information about kidney function)
 - Cardiac enzymes (gives information about your heart muscle)
- Electrocardiogram (ECG) (gives information about the electrical activity of your heart)
- Review of medications you are taking

1 Month Follow-Up:

After 1 month after procedure, you will be seen in the office or will be contacted by phone by the study staff, and will have the following assessments:

- Angina status (chest pain)
- Review of medications you will be taking
- Record all adverse events that occurred from the time you entered the study.

3 and 12 Months Follow-Up (for research purposes):

After 3 and 12 months, you will be scheduled to have two follow up visit to the cardiac catheterization unit, when you will receive a coronary angiography similar to one that you had when you received the stent, and a procedure called Optical Coherence Tomography (OCT). Both procedures are described below.



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Coronary Angiography Procedure:

A coronary angiography is an imaging test that uses x-rays to view the blood vessels that bring oxygen to your heart muscle, called coronary arteries. If they are narrowed or blocked, the lack of oxygen to the heart can cause a heart attack.

In the cardiac catheterization unit of the hospital, you will undergo a coronary angiography procedure. You will be prepared and directed to follow the instructions of your doctor for the coronary angiography. You will be given a local anesthetic (so you remain awake) and will likely be mildly sedated. The doctor will insert a catheter (flexible hollow plastic tube about the size of a pencil) into an artery in your arm or leg and move the catheter up into the arteries of your heart. A dye will then be injected through the catheter and a series of X-ray pictures will be taken. The coronary angiography procedure usually takes about 20 minutes and during the procedure you will also be monitored by an ECG machine.

Optical Coherence Tomography

Optical coherence tomography (OCT) is a diagnostic procedure that is used during cardiac catheterization, which uses light to create images of the inside of the coronary arteries. With OCT, doctors can obtain images of the blood vessels that are about the same as if they were looking under a microscope. The OCT is performed during the coronary angiography and uses a catheter called Dragonfly OPTIS. This catheter is not intended for use in the left main coronary artery, and is contraindicated in patients who are disqualified from Coronary Artery Bypass Grafting (CABG). The reason why this procedure is performed is to allow your doctor to look at the artery previously treated with the stent prior to your enrollment, in order to observe the healing process and to make sure that no new blockage reoccurred in the meantime.

At 3 and 12 Months follow up visits, you will also complete the following assessments:

- An interview to find out how you are feeling and to assess if you have any symptoms related to your cardiovascular disease or the implantation of the stent;
- A clinical assessment and physical examination;
- Blood Draw to assess:
 - Complete Blood Count (CBC) (gives information about cells in the blood stream such as white blood cells, red blood cells and platelets)
 - Urea and Serum Creatinine (gives information about kidney function)
- Cardiac enzymes (gives information about your heart muscle)
- Sub-study only: Electrocardiogram (ECG);
- Record of all medications;
- Angina status;
- Any medical care you have received.

POSSIBLE RISKS AND DISCOMFORTS

The known risks associated with the administration of an angiography to the left main coronary artery are:

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- Heart attack
- Stroke
- Injury to catheterized artery
- Irregular heart rhythm
- Allergic reaction to the dye or medications used during the procedure
- Damage to the blood vessel wall
- Kidney damage
- Excessive bleeding or blood clot
- Infection
- Radiation exposure from the associated imaging

The following complications have been described with the use of Optical Coherence tomography catheters:

- Coronary artery spasm
- Unstable angina
- Allergic reaction to the contrast media
- Kidney damage due to contrast media
- Arterial dissection, injury or perforation
- Blood clot formation, abrupt closure or total vessel occlusion
- Abnormal heart rhythms
- Embolism
- Acute myocardial infarction
- Death
- Catheter entrapment

There may be side effects that are not known at this time.

Women who are pregnant or nursing a child may not take part in this study. Before entering the study, you and your study doctor must agree on the method of birth control you will use during the entire study. If you think that you have gotten pregnant during the study, you must tell your study doctor immediately.

Other Risks

Risks of the usual care you receive are not risks of the research. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

NEW INFORMATION

All new findings discovered during the course of this research study that may reasonably influence your decision to continue to participate in this study will be provided to you by your study doctor, if such information is found.

**Participant Name:****Date:****Title of Study:** Boston Scientific Synergy Bioabsorbable Polymer Stent in Left Main PCI SOLEMN Study (Synergy OCT LEft MaiN)**Principal Investigator:** Mladen Vidovich, MD**BENEFITS**

There are no direct benefits to you from your taking part in this research study. However, the information we get from this study might help us treat future patients.

COSTS TO PARTICIPANTS AND PAYMENT

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

PAYMENT FOR PARTICIPATION

You will receive a \$50 compensation for travel to return for the 3 and 12-month follow-up visit.

ALTERNATIVE TREATMENT

You may choose not to participate in this study. If this is your decision, you can decline having the study follow up procedures.

You may discuss these options with your doctor.

CONFIDENTIALITY

If you participate in the research, your authorization will be required to have access to your private medical records. You will be asked to sign a separate authorization form to allow us to have this access. If you do not provide this authorization, you may not participate in the research.

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways:

Paper documents will be locked in a filing cabinet that is located in a locked VA office or restricted access area in the VA. Access to electronic research data will be limited to Principal Investigator and his/her designated study team and will be stored on a secure VA network server. Data will be stored with a code, without your name or identifiers. For security, the data and the master list linking your name and the code will be stored separately.

We will make every effort to keep the information collected for this study confidential.

We will include information about your study participation in your medical record.)

May I withdraw or revoke (cancel) my permission?

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.



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When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

Every reasonable effort to prevent any possible injury from this study will be taken. In the event the study results in any physical, mental or emotional injuries to you, VA will provide necessary medical treatment (not just emergency care) at no cost to you. This does not apply to treatment for injuries that result from if you do not follow the study procedures.

Note: The VA may not reimburse you for necessary medical care for treatment in non-VA facilities for injuries in research conducted collaboratively with VA by a non-VA organization.

Additional compensation, beyond paying for treatment, has not been set aside. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with Federal Tort Claims Act. For additional information concerning claims for damages, you may contact VA District Counsel at (708) 202-2216. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact:

DURING THE DAY: Dr./Mr./Ms. [Person First and Last Name] at [Phone number] [and/or Pager] and

AFTER HOURS: Dr./Mr./Ms. [Person First and Last Name] at [Phone number] [and/or Pager]

Emergency and ongoing medical treatment will be provided as needed.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

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Sometimes during the course of a research study, new information becomes available about the that is being studied that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

One of the research study personnel has explained the study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document._____
Participant's Name_____
Participant's Signature_____
Date_____
Name of person obtaining consent_____
Signature of person obtaining consent_____
Date